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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,076	01/19/2001	Stefan Thierfelder	Q-62705	9376

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT PAPER NUMBER

1644

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/764,076	THIERFELDER, STEFAN	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 08/737,798.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01192001</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/134,575, which is a divisional of U.S. Application Serial Number 08/737,798, which is a rule 371 continuation of PCT Serial Number PCT/EP95/01898.

Claims 1-5 have been canceled.

New claim 6 has been added and is currently pending in this application.

### *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for eliminating leukemic T cells, does not reasonably provide enablement for a generalized method for eliminating tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

Briefly, the claimed method is drawn to eliminating tumors in a tumor-bearing subject. The method comprises a first step of administering a first antibody that is capable of eliminating T cells in vitro, followed by a second step of administration of a second antibody that is capable of eliminating T cells in vitro, with the proviso that the two antibodies have constant regions that are of different isotypes and originate from different species.

The steps of the method are inconsistent with the treatment of "tumors" in general because the antibodies recited in the claim only eliminate T cells, not any other type of cell. An artisan would not be able to predict that the antibodies would be useful for the treatment of any type of tumor that is not a

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neoplasm of T cells. The specification only provides guidance for the use of antibodies that eliminate T cells, and such antibodies are not useful for the treatment of any type of tumor other than a cancer of T cells, such as leukemia.

Furthermore, there are no working examples in the specification of the use of the claimed method to treat any kind of tumor, including T cell cancers. While the presence of working examples is not required, without guidance on the treatment of tumors in the remainder of the specification, the artisan would need to rely upon the working examples for practice of the claimed invention. However, the working examples in the present specification only set forth a method for using anti-T cell antibodies for the elimination of T cells in patients with an autoimmune disease. Neither the examples nor the remainder of the specification disclose the treatment of any type of tumor. The specification discloses only, "the mouse model studies carried out by the inventors on the suppression of murine or human T cell leukemias transplanted into mice, a prolonged survival time due to antibody injection was observed. Upon T cell depletion, foreign immunocompetent cells can be introduced into chimeric mice, i.e., mice transplanted with bone marrow and suffering from leukemia, which foreign immunocompetent cells attack the neoplastic cells in the recipient" at page 7, lines 9-17 for example. Accordingly, the only tumor disclosed as being treatable by the method of T cell elimination exemplified in the specification or claims as originally filed is T cell leukemias.

In view of the breadth of the claims, the level of predictability in the art, the lack of working examples, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 6 is indefinite in its recitation of "and thus belongs to a different animal species than said second antibody." The recitation is merely narrative and does not effectively introduce any limitation into the claim, as it puts forth an incorrect conclusion. The fact that two antibody molecules possess different heavy chain constant regions does not necessitate that the antibodies be derived from different species. It is well known in the art that a species may possess multiple immunoglobulin isotypes, each of which is

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distinguishable from the others by the virtue of sequence/structural differences in its heavy chain constant region.

Claim 6 is ambiguous and unclear in its recitation of "capable of modulating the antigen effect of T cells" in lines 8-9. It is not clear what type of "antigen effect" a T cell might have and the phrase is not conventionally used in the art. Furthermore, the claim fails to state how "modulating the antigen effect of T cells" relates to "eliminating tumors."

*Conclusion*

3. No claim is allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
August 25, 2005

*RV*

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644